REMARKS

Claims 1-35 are pending in the subject application. Claims 1-19 have been withdrawn from consideration. Claim 20 has been amended and claim 36 added. Support for the amendment to claim 20 and for added claim 36 is found throughout the Specification and claims, as filed, and no new matter is presented by the amendment. Favorable reconsideration in light of the remarks which follow is respectfully requested.

1. 35 U.S.C. §102 Rejections

Claims 20-22, 25 and 26 have been rejected under 35 U.S.C. §102(b) as being anticipated by Jones (USPN 6015403). The Office asserts that

> Jones teaches all of the limitations of these claims. The use of the device of Jones teaches a method for performing an ophthalmic surgical procedure including the steps of providing a surgical device with an elongated body and a soft tip at the distal end that is easily visible during a procedure; making an incision in the eye; inserting the surgical device into the treatment area; performing a procedure; and removing the device. The visualization of the soft tip is enhanced by shining a light via a light source including a fiber optic probe onto the tip of the device and the treatment site.

Applicants respectfully traverse.

Applicants claim, in claim 20, a method for performing an ophthalmic surgical procedure comprising (a) providing a surgical device comprising an elongate body portion having a proximal end and a distal end and a soft tip at the distal end of the body portion, wherein the soft tip is at least partially colored so as to enhance a user's visibility of the soft tip in the surgical area; (b) making an incision in the eye of a patient to access the treatment area; (c) inserting the surgical device into the treatment area through the incision; (d) performing the ophthalmic surgical procedure using the surgical device; and (e) removing the surgical device from the treatment area, wherein the ability to visualize the soft tip during the ophthalmic surgical procedure is enhanced.

Applicants have found that when conventional cannulas are used during ophthalmic procedures, it is often difficult for the surgeon to precisely see and position

the cannula tip, which can lead to problems in the procedure. In particular, conventional cannulas utilize soft, transparent materials in forming their tips. These transparent tips are difficult for the surgeon to discriminate during use, particularly during the fluid/air exchange when visibility is compromised by bubbles and a significant change in the refractive media from fluid to air.

With this in mind, Applicants have developed improved cannulas having tips that are designed to enhance their visibility in the surgical area, thereby providing safe and easy manipulation of the device around the particularly delicate eye area.

Jones describes an ophthalmic probe which includes a handpiece which terminates distally in a needle and wherein the needle has a soft tip. According to Jones, an optical fiber extends through the needle and transmits light to the eye. However, Jones does not describe or suggest that the ophthalmic probe is used to perform the ophthalmic surgical procedure as set out in Applicants. Rather, the device described by Jones is a probe, which is a well-known device used in exploring bodily cavities. The probes described by Jones are used solely for this purpose and are not used in performing surgical procedures.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

It is clear from the foregoing remarks that claim 20, as well as new claim 36, are not anticipated by the Jones reference. Claims 21, 22, 25 and 26 depend from claim 20 and, likewise, are not anticipated by Jones.

Accordingly, reconsideration and withdrawal of the 35 U.S.C. §102 rejections is respectfully requested.

2. 35 U.S.C. §103 Rejections

Claims 23, 24 and 27-30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Jones (USPN 6015403) in view of Waner et al. (USPAP 2002/0115922). The Office asserts that:

> Referring to claims 23 and 24, Jones teaches all of the limitations of these claims as described above except for the step of causing the soft tip to glow or fluoresce. Waner et al. teach a medical device that includes an elongated body that is marked by areas of varying optical properties such that a user can easily visualize and monitor the position of the device. It would have been obvious to one of ordinary skill in the art at the time of invention that the tip of the device of Jones could be made with varying optical properties as in Waner et al. including the ability to glow when light is shone upon it in order to facilitate the visualization of the tip by a user during a procedure (see paragraphs 0011-0013 of Waner et al.).
>
> Referring to claim 27 and 30, Jones teaches all of the limitations of these claims as described above except for the coloring of the soft tip. Waner et al. teach a medical device that includes an elongated body that is marked by areas of varying optical properties such that a user can easily visualize and monitor the position of the device. It would have been obvious to one of ordinary skill in the art at the time of invention that the tip of the device of Jones could be made with varying optical properties as in Waner et al. including the coloring of the device of Jones could be made with varying optical properties as in Waner et al. including coloring the tip with fluorescent material in order to facilitate the visualization of the tip by a user during a procedure.
>
> Referring to claims 28 and 29, Jones teaches all of the limitations of these claims as described above except for the coloring of the soft tip. Waner et al. teach a medical device that includes an elongated body that is marked by areas of varying optical properties such that a user can easily visualize and monitor the position of the device. It would have been obvious to one of ordinary skill in the art at the time of invention that the tip of the device of Jones could be made with varying optical properties as in Waner et al. including the marking of the tip with a fiducial ring in order to facilitate the visualization of the tip by a user during the procedure.

Applicants respectfully traverse.

As acknowledged by the Office, Jones does not teach "the step of causing the soft tip to glow or fluoresce" (claims 23 and 24), "coloring of the soft tip" (claims 27, 28, 29 and 30).

Rather, the Office relies on Waner as assertedly describing these features. However, Applicants note that the earliest priority date of Waner is February 12, 2001. The present application has a priority date of October 18, 2000 (Applicants' U.S. Provisional Application Serial No. 60/241,496). Thus, Waner does not qualify as prior art.

Accordingly, claims 23, 24 and 27-30 are patentable over the cited references. Reconsideration and withdrawal of the 35 U.S.C. §103 rejections is respectfully requested.

The Office further asserts that:

> Referring to claim 31, Jones teaches all of the limitations of these claims as described above except for the use of the device in a vitrectomy procedure. Jones also teaches that the surgical device may be an aspirating device. Helfgott et al. teach a similar device that may be used to perform a vitrectomy including the steps of cutting the vitreous body from the retina; removing the body, pushing the retina against the wall of the eye; draining subretinal fluid; and allowing fluid from the blood to fill the vitreous cavity. It would have been obvious to one of ordinary skill in the art at the time of invention that the device of Jones et al. could have been effectively used in a vitrectomy procedure as in Helfgott.
>
> Referring to claims 32-34, the combined device and method of Jones and Helfgott et al. teaches all the limitations of this claim as described above. It would have been obvious to one of ordinary skill in the art at the time of invention that the aspirating device of soft tip could have been used to drain subretinal fluid in order to perform the vitrectomy effectively.
>
> Referring to claim 35, the combined device of Jones and Helfgott et al. teaches all of the limitations of this claim as described above. Also, Helfgott et al. teaches that the tip of the device may include an abrasive surface to remove scar tissue from the eye (column 15, lines 3-20). It would have been obvious to one of ordinary skill in the art at the time of invention that the combined device and method of Jones and Helfgott et al. could include a tip with an abrasive surface in order to remove scar tissue from the eye during a procedure.

As set out above, Jones describes an ophthalmic probe that transmits light to the eye. Such devices are well-known and are designed for exploring bodily cavities. Jones indicates that the probe can include aspiration means. During surgical procedures, it is common to provide an aspiration device to remove blood and other material from the surgical area so that the surgical area is clear and more easily viewed without the obstruction of blood and other material. Thus, Jones combines the light transmission aspect, which enhances a surgeon's view of a surgical area, with an aspiration means, which also enhances a surgeon's view of a surgical area by removing unwanted materials from the area. Jones only describes use of the probe to transmit light into the surgical area and to suction material from the surgical area. There is no suggestion to provide, in addition to the light transmission and aspiration aspects, means for performing a vitrectomy by cutting nor to use the probe to perform a vitrectomy. Helfgott describes a device for surgical cutting. The Helfgott device is a very different type of device than that described by Jones: while Jones describes a probe, Helfgott describes a cutting tool. The Helfgott device has a rigid, beveled cutting tip fabricated of an inner tubular member and an outer tubular member. The inner tubular member is axially slidable within the outer tubular member such that material drawn into the device is cut when the inner tubular member is drawn through the outer tubular member.

Applicants respectfully submit that the Jones device describes a soft tip device that is used to transmit light to a bodily cavity. The Jones device does not describe or suggest providing a cutting means or how such a cutting means could be incorporated within the soft tipped device. The Helfgott device is a cutting device that includes a rigid, beveled cutting tip and two coaxial rigid tubes that cut material between the tubes as the rigid tubes are axially moved with respect to eachother.

As the Federal circuit has stated, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260,1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). Obviousness may not be established using hindsight or in view of the teachings or suggestions of the

inventor. *Para-Ordance Mfg. v. SGS Importers Int'l, Inc.*, 73 F.2d 1085, 1087, 37 USPQ2d 1237, 1239 (Fed. Cir. 1995).

Applicants respectfully submit that there is no suggestion in the art to modify the Jones device as set out by the Office. Jones describes an ophthalmic probe, which is a known device that is designed for exploring bodily cavities. Such devices are not typically used in performing surgical procedures such as cutting. The Helfgott reference describes a cutting tool. Applicants respectfully submit that there is no suggestion to modify the probe described by Jones to incorporate a cutting mechanism nor to use the Jones' probe as a cutting surgical device to perform a vitrectomy. Rather, this teaching comes purely from Applicants' invention.

Further, Applicants respectfully submit that Jones teaches away from providing a probe wherein a rigid portion, much less a cutting portion, can contact the eye. As set out by Jones:

> [T]he prior art system can be further improved. The eye is a fragile organ and can be easily injured. The probe, which is inserted into the eye, is generally made from stainless steel. This is, of course, a rigid material, which, if inadvertently brought into contact with various structures of the eye, such as the retina, could easily injure the eye. (Col. 1, lines 30-35)

Thus, according to Jones:

> Another object is the provision of such a system which will protect the eye from accidental contact with the probe to reduce injury to the eye. (Col. 1, lines 42-44)
>
> The distal end 41 (see FIGS. 3 and 4) of needle 25 is provided with a tip 43 made of a soft pliable material, preferably silicone. This soft tip serves as a buffer between the structures of the eye and the metal portion of probe 25 (labeled 25A in FIG. 4), to prevent accidental injury to the eye structure caused by contact of the eye structure with the metal portion 25A of the needle (Col. 3, lines 29-36).

Jones points out that the problem with prior probes is that they are typically made of a rigid material such as stainless steel, which can injure the eye the tip of the probe contacts the various structures of the eye. Thus, Jones eliminates the potential

for injury by providing a distal tip that is soft so as to protect the eye from contact with the metal portion of the probe.

Applicants further disagree with the Office's assertion that, referring to claim 35, "It would have been obvious to one of ordinary skill in the art at the time of invention that the combined device and method of Jones and Helfgott et al. could include a tip with an abrasive surface in order to remove scar tissue from the eye during a procedure." Such an abrasive surface is specifically taught away from by the Jones reference as set forth above. Jones' probe is specifically designed to eliminate portions that could potentially contact and injure various portions of the eye. An abrasive surface on the tip of the Jones probe would do exactly what the Jones device is specifically designed not to do.

Accordingly, claims 31 and 35 are patentable over Jones in view of Helfgott. Claims 32-34 depend from claim 31 and, likewise, are patentable over Jones in view of Helfgott. Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

Reconsideration and allowance of claims 20-36 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

Date: Nov. 17, 2003

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